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Ravensburg District Court

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recorded in the open session of the District Court Ravensburg, 4th civil chamber, on Thursday,- 12.03.2015 in Ravensburg

Present:
Presiding Judge at the Regional Court Schneider
as Presiding Judge
Judge Dr. Brutscher Judge at
the Regional Court Percic
Pursuant to Section 159 (1) of the German Code of Civil Procedure (ZPO), a court refrained from calling a court reporter.

In the litigation

[redacted]

Attorney-in-Fact:
Lawyers **Gebhardt & Kollegen,** Eisenbahnstrafse 47/corner Sieberstrafse, 66424 Hom burg, Gz.: 60453 RVB/kr

against

Dr. Stefan **Lanka,** Ludwig-Durr-Weg 5/2, 88085 Langenargen, Germany
- Defendant -

Attorney-in-Fact:
Lawyers **Wagner - Barth,** Bahnhofstrafse 1, 66663 Merzig, Germany, Gz.: 13-833-12

due to award of contract

appear when the matter is called:

The plaintiff with attorney Dr. Gebhardt,

the defendant with attorney Barth and Assessor Schreiner, the expert Prof. Dr. Dr. Podbielski.

Dr. Gebha[dt, attorney at law, presents by reference the **motions from the statement of claim** dated November 20, 2013, sheet 2, and from the **supplemental statement** dated August 1, 2014, sheet 80. -

Attorney Barth moves to **dismiss the action.**

The supplementary hearing of the expert is entered into.

He explains

about the

person:

Prof. Dr. Dr. Andreas **P o d b i e l s k i**., Institute of Medical Microbiology, Virology and Hygiene, University Medical Center Restock, Schillingallee 70, 18057 Restock, Germany, 59 years old, university professor, not related to the parties and not related by marriage.

To the point:

I will first make my written opinion of November 17, 2014 and my supplementary opinion of March 3, 2015 the subject of my comments today.

In addition, I can answer the Chamber's questions:

In general, in biology, one should be careful with the concept of "evidence", we actually only speak of "evidence".

When it comes to the connection between microorganisms and diseases, two questions must be kept apart. On the one hand, there is the question of whether a particular microorganism exists at all and what its nature is; on the other hand, it may need to be clarified whether it is actually causally significant for the disease; the presence of the microorganism alone does not prove such a causal relationship.

As far as the existence of the microorganism is concerned, there are many basically equivalent ways to collect evidence. Typically, in biology, we require that two independent paths be followed to prove the existence of a microorganism.

and to classify this taxonomically.

The classical way is the optical detection with microscopic methods. In the case of viruses, it is even necessary to work with an electron microscope. In this context, the question of size always arises. However, the images and the question of size are normally of secondary importance. The images are open to any interpretation and, taken by themselves, have little probative value, but only make things clear.

Secondly, the components of a pathogen can be detected. Only proteins, carbohydrates and nucleic acids can be considered as such. Usually all three are present. Here one can work with purification and detection methods.

With a pathogen, one would typically expect that it can multiply. Hence the method of cultural detection of this germ. This method is problematic in that it does not always work because, for example, the multiplication of a germ in the laboratory cannot be easily imitated. This applies to a large proportion of the germs known today.

A further step may then be to consider the multiplication of the nucleus as a purification step and then to examine the pathogen again under the microscope to see whether its appearance has not changed; it may also be checked whether the biochemistry of the nucleus is still the same as before.

In the meantime, these methods have been joined by the possibility of isolating and fully sequencing the nucleic acids. From the outset, this represents an independent side path, which can itself also be important for the provision of evidence.

For this latter method, there is a prominent example with the hepatitis C virus, which was never cultivated at all, but was analyzed immediately in its genome sequence. The nucle insauresequence in the measles virus, for example, also made it possible to produce this microorganism fully synthetically in the test tube. On the one hand, this method is not entirely simple, and on the other, it is subject to ethical questions. However, this shows the strength of the nuclear acid sequence.

Alie these so far erorterten methods concern however only the existence of the Keirn per se, still

not its function as a pathogen.
As I understood the tender, however, it was probably only a question of existence per se.

At the request of the court, the expert explained the meaning of Henle-Koch's postulates in more detail, at least as a precautionary measure, with regard to the causal relationship between the microorganism and the disease:
These postulates are a mental stutze from a time when people had just learned,
that there may be a connection between microorganisms and infectious diseases. In their original formulation, the postulates were aimed at pathogens known at that time, i.e., since about 1850, long before viruses were known as such. This latter circumstance at the same time illuminates the problem of applying certain rules to objects that are not known at all until after the rule has been formulated.

In their classical form, Henle-Koch's postulates consist of four parts, as already explained in my report. Because it has been found that for certain pathogens, which in themselves are recognized, these postulates for the proof of causality cannot be fully adhered to, the postulates have been extended by typically three points. One is the aspect of defensive reaction, which only emerged at the beginning of the 20th century. One discovered things
such as antibodies or defense cells, with which the organism specifically combats the pathogens.
Secondly, it was formulated that cytopathology in in vitro experiments should be similar to that in humans. This requirement is particularly important for viruses that do not live independently outside a human host organism.
Finally, the question is whether selective eradication can contribute to clinical recovery of the patient.

With these three extensions, in varying combination with the original postulae, one can and must apply these postulates to all pathogens known today.

Nowadays, there is also the genome sequence. In principle, one can read in the genome sequence like in a book. With a very high degree of probability, statements can be made about how an organism with a certain genome sequence behaves and what characteristics it displays.

When asked by the court whether it is possible to prove the causality of infection for a pathogen in this latter form exclusively on the basis of genome guideline: No, it is not possible exclusively in this form. Here, one can only achieve computer models with correspondingly high probability values, but no direct seleg. -

According to dictation up to here, the expert completes on his own:
I must make it clear that we cannot comprehensively deduce the characteristics or behavior of an organism from the genome sequence alone. We can only determine structural features and predict with greater or lesser probability how the organism will behave in a certain way; a comprehensive statement on the overall behavior of the organism is not possible.
the genome sequence does not yet allow either.

Upon further question by the Board:
Of the total of certainly more than 10,000 scientific articles on measles, a large part is concerned with references to the disease, its detection and control. With regard to the articles presented by the plaintiff, it should first be noted that the contribution by Enders & Pee ble_s1954 is certainly fundamental; it was the first article ever on this question. How one wanted to evaluate the selection in the i.ibrigen, is perhaps also question of taste. There may be
There are many other articles that could have presented the chain of evidence or the chain of evidence in the sense of the call for proposals even more clearly in one place or another.
but I stand by my assessment that the six articles submitted, taken together, meet the conditions of the RFP.

The meeting is briefly interrupted.

After reconvening with the above-mentioned parties, the Board discusses the understanding of the claim and points out that, in the Board's opinion, the claim should be very clearly understood to mean that not only the mere existence of a certain microorganism should be proven, but also its causality for measles disease.

In response to a question from the court, as to whether the summary of the evidential value of the submitted

The expert explains that the article may be understood not only in terms of the existence of microorganisms, but also in terms of their pathogenicity:

This may indeed be understood as far as it goes. These articles deal practically throughout not only with the existence of the microorganism, but also with its pathogenicity. I have also explained this in detail in my expert opinion, particularly with regard to Henle-Koch's postulates. With regard to the pathogenicity of the microorganism, I therefore maintain that the articles presented, taken together and in particular with the inclusion of the 1995 review article and the work cited therein, also provide evidence of the pathogenicity of the measles virus.

Upon further inquiry by the Board, the expert explained why, despite methodological criticism of the individual original papers, he considered the proof of causality in the articles submitted by the plaintiff to be established:

I must point out that, of course, any scientific journal that publishes

The way to deal with such weaknesses in a scientific context is to submit a scientific article of one's own and discuss the issues.

Now, as far as the individual original articles are concerned, I can export:

The contribution of *Enders* & *Peebles* 1954 in any case fulfills Henle-Koch's postulates of classical formulation No. 1 and 2. It even adds a certain biochemical characterization (temperature sensitivity) and a statement on the size.

In the contribution of *Bech* & *von Magnus* 1958 then also the third classical Henle-Koch postulate is fulfilled. We have additionally proved in this contribution the defensive reaction which is relevant in the extended version of these postulates as stated. In fact, however, an experiment in the sense of the 4th classically formulated Henle-Koch postulate was not carried out at that time.

As for the other three original papers, these deal ma geblich with gro e and electron microscopic imaging of measles virus and fall out of this assessment to some extent.

The 1995 review article cites and then presents several more articles which, with respect to the measles virus, fulfill all postulates No. 1 to 4 in the classical formulation. Therefore, it can be stated that the presented articles indeed prove Henle-Koch's postulates in the classical formulation. In addition, as already mentioned, there is the defensive reaction

as well as a specific cytopathology, namely the formation of syncytia, i.e. cell fusions.
The virus is considered to be a typical paramyxovirus, which includes the measles virus.

When asked by the court:
I cannot say now whether there is an article that comprehensively presents the same things as the original articles mentioned without showing their methodological weaknesses, i.e., for example, with the negative controls that are indeed to be missed. In this context, I would like to point out again that certain parts of the experimental design in the original articles of '54 and '58 do have a certain control function.
The following seems to me to be decisive: Such scientific articles are also used for follow-up work by other scientists. A good purification mechanism has been established in the scientific literature, which, especially in recent times, has in part led to the publication of arti
kel from high-ranking scientific journals. If the processes described in the article could not be reproduced at all in subsequent trials, this is typically the case in articles by other researchers. In any case, this would certainly have been expected for a topic such as measles, which is the subject of such intensive research.

The expert completes on his own initiative:
It's fair to say that once certain things have been widely accepted in the scientific world, it's not easy to publish contrary results, and you have to fight against that. On the other hand, however, it is an extremely high incentive for scientists to publish new and better findings, especially in the case of a widely accepted subject, if only in terms of reputation. Experience also shows that such refutations can then be published at a very high level. Against this background, too, one must really expect, despite all the difficulties, that a publication will be found for well-documented results to the contrary.

In response to a question from Assessor Schreiner as to whether the distinction made by the expert between proof and seleg meant that proof of the circumstances at issue here was ultimately not required:
I have to clarify that in biology, evidence in the classical sense, such as in mathematics or physics, cannot be given. In biology, only evidence can be collected from the outset, which at some point in their aggregation practically acquires probative value.

Upon follow-up by Assessor Schreiner, whether this circumstance narrows the probative value:
No, the way biological research has been conducted for many decades, that is not the case.

In response to a question from Assessor Schreiner, he asked whether the criticism of the early original papers, e.g., that the 1954 paper did not fulfill Henle-Koch's Postulate 3, did not mean that these papers were unusable or whether it was at all possible to make a distinction between such papers:
It is not the task of technical articles on microbiological matters that each technical article in itself fulfills all four of these Henle-Koch postulates; as we can see, some articles do not deal with them at all. Each article has its own scope and content. If one wanted to satisfy in one article the requirements of all four Henle
le-Koch's postulates, the article would have been so voluminous that it might not have been publishable at all in view of the editors' specifications. Taken in isolation, therefore, this is not a shortcoming.

Upon follow-up by Assessor Schreiner, whether beyond editor's specifications then perhaps books or dissertations of corresponding kind existed:
Dissertations are difficult to see. An original monograph, which for the first time represents own investigations, in the kind inquired would be me not known.

In response to a question from Assessor Schreiner, he asked whether the previously stated assessment of the expertise of the publications mentioned in the 1995 review article did not mean that there were indeed publications that fulfilled all four of Henle-Koch's postulates:
I must clarify that my previous statement was not meant in this sense. I can only say that individual aspects of the later works presented in the review article can also be evaluated as fulfillment of certain Henle-Koch postulates. I really do not know of a single work which in itself fulfills all four postulates.

In response to a question from Assessor Schreiner, he asked whether, in addition to the control system mentioned by the expert, the classification of a publication as a "scientific publication" did not also require further controls to ensure that the experiment had been carried out properly and, in particular, that it had been documented:
The obligations to document what is behind a professional article have changed in the

The last 50 years have seen some serious changes in this area. An essential aspect in this respect are the possibilities available today, especially through the electronic media, which make it possible to provide data to a much greater extent. The documentation requirements for scientific journals were certainly much narrower in the 1950s than they are today.

In response to a question from Assessor Schreiner, he asked whether it would not be terribly easy to make up for the attempts made at that time with today's means and to publish an article today that would not be subject to any methodological criticism:
In my report and the supplementary statement, I have already explained that, on the one hand, there is an economic efficiency requirement for research institutions; no financier will provide funding to prove things that are already known in the scientific community.
can be considered as proven. One will not find any publication organ for such works.

On interjection of Assessor Schreiner. that the provability represents just a problem: - In any case, the overwhelming mass of scientists understands these things as proven.

In response to a question from Assessor Schreiner, what are the components of the measles virus, in particular whether the measles virus contains ribosomes:
No, the measles virus does not contain ribosomes. The common definition of the virus is that it does not have ribosomes.

Assessor Schreiner then addresses the defendant's alleged communication from the Robert-Koch Institute that the measles virus contains ribosomes: in response to his question whether such a statement would not, as it were, throw the whole concept of the measles virus into disarray: "Such a statement would indeed be quite astonishing, it would attract the greatest attention in the scientific community and could be published with the prospect of great impact. The concept of the virus, however, was not necessarily overturned by this; the conceptual understanding of the virus is certainly in a state of flux.

The expert completes on his own initiative:
I would like to clarify that this latter statement concerns the concept of the virus as a whole. For example, viruses have been described that are much larger than bacteria. This raises difficult taxonomic questions. With regard to the measles virus, however, such questions arise.

not at present.

In response to a question from Assessor Schreiner, he asked whether the expert also considered a summary of publications that had already appeared without reproducing his own research results to be a scientific paper:

Yes, of course.

In response to a question from Assessor Schreiner, he asked whether this also applied in particular to the review work from 1995 submitted by the plaintiff:

Yes, this paper has been published in a peer-reviewed journal. Such reviews are also examined in advance, on the one hand for the consistency of the presentation and conclusions drawn, and on the other hand for the inclusion or exclusion of relevant articles. The inclusion of one's own research results is, by the way, a mandatory prerequisite for this type of publication; care is taken to ensure that there is no confusion here.

Upon follow-up by Assessor Schreiner, whereupon the examination would take place:

Whether in fact those parts of the original articles that are reproduced in such a review are correctly reproduced and whether the relevant parts are also selected; on the other hand, in such a review new conclusions are drawn from the various original articles (each of which drew conclusions from its research results). The review of the review article is to see whether these new conclusions appear coherent and consistent.

When asked by Assessor Schreiner whether the expert could now readily indicate which original articles cited in the 1995 review fulfilled Henle-Koch's postulates 1 to 4:

No, I can't do that off the cuff. But I must remind you that it's not at all compulsory.

In general, all four postulates must be fulfilled for a pathogen to be accepted as such. As already mentioned, there are recognized pathogens for which not all four postulates can be fulfilled at all.

The meeting was adjourned for consultation and then continued with the above-mentioned parties.

sets.

When asked by Assessor Schreiner how big1 the measles virus was now:
I have already explained in detail in my expert report that and why it is a question of variable gror.ies, which can be found in the literature on this subject.

When asked by Assessor Schreiner. if all six items submitted were listed:
Yes, as far as I know, the NCBI database only lists articles from peer-reviewed journals.

In response to a question from Assessor Schreiner. how the typical changes of the cell mentioned on the one hand relate to the different sizes or shapes presented on the other hand in relation to the article by *baikoku and others in* 2007:
To do this, I actually had to read through the article again carefully. I can't say anything about that here and now.

No further questions are addressed to the expert.

The expert approves his data according to loud dictation and under all-around out - pressure/ich waiver of reaudition .

. The parties are disputing the result of the evidence and the merits of the case with the motions stated at the beginning.

No further motions are made.

The meeting is interrupted once again.

After recall, the following verdict shall be pronounced by reading out the verdict formula:

1. The defendant is ordered to pay to the plaintiff:

   a) EUR 100,000.00 plus annual interest thereon at a rate of 5 percentage points above the respective prime rate since May 1, 2012,

   b) EUR 2,924.07 in extrajudicial costs,

   c) EUR 492.54 plus annual interest thereon at a rate of 5 percentage points above the respective prime rate since April 16, 2014.

2. The costs of the proceedings shall be borne by the defendant.

3. The judgment is enforceable in advance against a security deposit of 110% of the amount to be enforced.

The expert is discharged unsworn at 12:30.

Schneider
Presiding Judge at the Regional Court

Rief, JHSecretary
as the registrar of the office at the same time for the correctness and completeness of the transfer from the sound carrier.

Certified
Ravensburg, 13.04.2015

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Anlage zum Prot.

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3. Das Urteil ist gegen Sicherheitsleistung in Höhe von 110 % des jeweils zu vollstreckenden Betrages vorläufig vollstreckbar.

Leuchs Prasse Probst-Scher